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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/435,471 11/08/99 COOPER

D 114205.1200

021269  
PEPPER HAMILTON  
600 FOURTEENTH STREET NW  
WASHINGTON DC 20005

HM12/0328

EXAMINER

BAKER, A

ART UNIT

PAPER NUMBER

1632  
DATE MAILED:

03/28/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p>09/435,471</p>	<p>Applicant(s)</p> <p>COOPER ET AL.</p>	
	<p>Examiner</p> <p>Anne M. Baker</p>	<p>Art Unit</p> <p>1632</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-25 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 20) <input type="checkbox"/> Other: _____.                                   |

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### DETAILED ACTION

Claims 1-25 are pending in the instant application.

#### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 and 19-25, drawn to a nucleic acid construct, a method of nucleic acid analysis, a recombinant cell, primers, a kit comprising primers, a nucleic acid probe, and a vector, classified in class 536, subclass 24.1.
- II. Claims 8 and 9, drawn to a transgenic animal, classified in class 800, subclass 13.
- III. Claims 10 and 11, drawn to an antisense nucleic acid, classified in class 536, subclass 24.5.
- IV. Claims 12-18, drawn to a method for controlling gene expression and methods of treating various disorders, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are patentably distinct, one from the other because the inventions are drawn to materially different compositions and distinct methods. The nucleic acid constructs, cells, primers, probes, and vectors of the invention of Group I are chemically, biologically, and functionally distinct from the transgenic animal of the invention of Group II and the antisense molecules of the invention of Group III. Although some nucleic acid constructs could be used to make the transgenic animals, their use is not limited to making transgenic animals, as they can also be used to transform host cells. Although some of the compositions of the invention of Group I could be used in the methods of the invention of Group IV, their

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use is not limited to these methods, as they can also be used to transform host cells. The transgenic animals of the invention of Group II are chemically, biologically, and functionally distinct from the antisense molecules of the invention of Group III. The transgenic animals of the invention of Group II are not required to practice the methods of the invention of Group IV. The antisense molecules of the invention of Group III are not required to practice the methods of the invention of Group IV. Thus, the compositions and methods of the inventions of Groups I-IV are patentably distinct, each from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

Anne-Marie Baker, Ph.D.

*Anne-Marie Baker*  
**ANNE-MARIE BAKER**  
**PATENT EXAMINER**